B2

wherein said amphipathic lipid has an average particle size of 0.5 to 150 µm and is dispersed in said surfactant and aqueous medium.

(New) The dispersion of claim 11, wherein said surfactant (b) is selected from the group consisting of a nonionic surfactant, an anionic surfactant, an amphoteric surfactant and a mixture thereof.

73. (New) The dispersion of claim 12, wherein said nonionic surfactant is selected from the group consisting of a alkyl polyglycoside, a polyoxyalkylene alkyl ether, a polyoxyalkylene alkenyl ether, a polyoxyalkylene sorbitan fatty acid ester, a sorbitan fatty acid ester and a mixture thereof.

14. (New) The dispersion of claim 11, wherein a component (a)/component (b) weight ratio ranges from 90/10 to 25/75.

15. (New) The dispersion of claim 11, wherein component (a) is a substance analogous to ceramide.

(New) A process for preparing a dispersion as claimed in any one of claims of to 3, which comprises heating the component (a), the component (b) and water to a temperature not less than the melting point of the component (a), thereby fusing them; and cooling to crystallize the component (a).

17. (New) A washing-away type cosmetic composition, which comprises the dispersion of any one of claims 11 to 13.

18. (New) A process for preparing a washing-away type cosmetic composition, which comprises mixing the dispersion of any one of claims 11 to 13 with the components of the cosmetic composition other than the dispersion, at not more than 50° C.

19. (New) A washing-away type competic composition comprising:

(A) 0.01 to 10 wt.% of an amphipathic lipid having an average particle size of 0.5 to 150 μm, and having in the molecule thereof, at least one hydroxy group and at least one amide group; and

(b) 5 to 95 wt.% of a surfactant.

SUPPORT FOR THE AMENDMENT

Support for Claims 11-19 is found in claims 1-10 as originally presented. No new matter would be added in this application by entry of this amendment. Upon entry of this amendment, Claims 11-19 will now be active in this application.

REQUEST FOR RECONSIDERATION

The present invention is directed to a dispersion of an amphipathic lipid in a surfactant and aqueous medium.

Applicants wish to thank Examiner Wells and Supervisor Patent Examiner Dudash for the helpful and courteous discussion held with their U.S. representative on May 4, 2001. At that time, Applicants' U.S. representative argued that the prior art reports difficulties in formulating compositions comprising an amphipathic lipid at concentrations greater than 2 wt.% (page 2, lines 3-22 of the specification) and that the present invention addresses the problem by providing a dispersion of an amphipathic lipid in a surfactant and aqueous medium. The following is intended to expand upon the discussions with the Examiner.

Amphipathic lipids such as ceramide are reported as components in hair and skin compositions. Formulations of such materials in an amount greater than 2 wt.% can be difficult due to the melting temperature of these materials. Attempts to address this problem

by dissolving the ceramide and then emulsification have produced diminished effects.

Accordingly, amphipathic lipid compositions which provide for improved concentration are sought.

The present invention addresses the problem by providing a dispersion of an amphipathic lipid dispersed in a surfactant and aqueous medium in which the amphipathic lipid has an average particle size of from 0.5 to 150 µm. Applicants have discovered that such an amphipathic lipid dispersion provides for increased concentrations of lipid while retaining the desirable effects. Such a dispersion is nowhere disclosed or suggested in the prior art of record.

The rejection of Claims 1-3 under 35 U.S.C. §102(b) over <u>Pillai et al</u>, U.S. 5,476,661, is respectfully traversed.

This reference reports a composition comprising 25-hydroxycholecalciferol, a lipid and a vehicle for the hydroxycholecalciferol and lipid. The reference does not describe the lipid component as a dispersion in surfactant and aqueous medium and average particle size of 0.5 to 150 µm. In addition, in Examples 4 and 6-11, the concentration of ceramide never exceeds 1.5 wt.%, consistent with Applicants' description on page 2, line 17 of the specification.

In contrast, the present invention is directed to a dispersion of amphipathic lipid and surfactant in aqueous medium in which the average particle size of the lipid is from 0.5 to 150 µm. Applicants note that the claims have been amended to recite a particle size for the amphipathic lipid. Since the cited reference nowhere discloses or suggests such a particle size for the lipid component dispersed in surfactant and aqueous medium, the present

invention is clearly not anticipated nor obvious from this reference and accordingly withdrawal of the rejection under 35 U.S.C. §102(b) is respectfully requested.

The rejection of Claim 10 under 35 U.S.C. §103(a) over <u>Pillai et al</u> in view of <u>Vanlerberghe et al</u>, U.S. 5,985,255, is respectfully traversed.

The Examiner concedes that Pillai et al fails to disclose the average particle size of the lipid component. The Examiner relies on Vanlerberghe et al as teaching a particle size of 0.1-200 μm (column 1, line 14). This particle size is for a solid, liquid or pasty perfumed composition and the particle size refers to a wax component which serves as a vehicle for the perfume (column 1, lines 10-16). This has nothing to do with the primary reference of a topical application for hair and skin and accordingly, there would be no motivation to provide the lipid component of Pillai et al at a particle size of 0.1-200 μm. The very reason the reference teaches a particle size of 0.1 to 200 μm is to serve as a vehicle for perfume.

Accordingly, why would one of skill in the art of hair, skin and nail care (the subject matter of Pillai et al, be motivated to formulate the lipid component of the skin composition of Pillai et al, to have an average particle size of from 0.5 to 150 μm? The lipid component of Pillai et al, is not a perfume vehicle and accordingly, there is no motivation to provide the lipid component of Pillai et al, as a dispersion having a particle size of from 0.5 to 150 μm.

Moreover, Vanlerberghe et al is directed to wax microemulsions in a liquid vehicle in which the particles have a size of less than 0.5 μ m (column 2, lines 21-26). As such, independent of the motivation to combine the teachings of this reference with Pillai et al, the reference teaches a particle size of less than 0.5 μ m and in no way suggests an average particle size of from 0.5-150 μ m.

Since the cited combination of references teaches at best a particle size of less than 0.5 μ m, and the claimed particle size ranges from 0.5-150 μ m, the claimed invention is clearly not obvious over the cited combination of references and accordingly withdrawal of the rejection under 35 U.S.C. §103(a) is respectfully requested.

The rejection of Claims 1-3 and 10 under 35 U.S.C. §112, second paragraph, is obviated in-part by appropriate amendment and traversed in-part.

Applicants have rewritten the claims to clearly recite that the amphipathic lipid has therein at least one hydroxy group and at least one amide group. Such a description is sufficient for those of ordinary skill in the art to understand the metes and bounds of the claimed invention. Accordingly, withdrawal of the rejection under 35 U.S.C. §112, second paragraph, is respectfully requested.

With respect to Claims 2 and 3, Applicants have now rewritten Claims 2 and 3 as claims 12 and 13 to recite the appropriate alternative language.

With respect to Claim 10, Applicants respectfully submit that the term "washing-away" is sufficiently clear to those of ordinary skill in the art such that the metes and bounds of the claimed invention are clear. Moreover, since the term appears in the preamble of the claim, the definiteness of the claimed subject matter would be clear to those of ordinary skill in the art. In view of Applicants' amendments and arguments, withdrawal of the rejections under 35 U.S.C. §112, second paragraph, is respectfully requested.

Regarding Applicants' request for priority, Applicants note that a certified copy of Applicants' priority documents filed on December 21, 1999. Since no interference has been declared and no intervening reference has been cited by the Examiner, no English translation

is needed at this time (37 C.F.R. §1.55(a)). Full benefit to priority as requested is respectfully requested.

Finally, with respect to the term "amphipatic" as it appears throughout the specification, Applicants respectfully submit that this is an obvious typographical error, the correction of which being clear to those of ordinary skill in the art --amphipathic--. As the meaning is clear to those of ordinary skill in the art no change to the specification has been made at this time. Should the examiner maintain this to be an issue, the examiner is requested to contact Applicants' U.S. representative as the phone number below to make these changes by Examiner's amendment.

Applicants submit that this application is now in condition for allowance and early notification of such action is earnestly solicited.

Respectfully submitted,

OBLON, SPIVAK, McCLELLAND, MAIER & NEUSTADT, P.C.

Norman F. Oblon Attorney of Record Registration No. 24,618

Richard L. Chinn, Ph.D. Registration No. 34,305

22850

(703) 413-3000

Fax No.: (703) 413-2220

RLC\la

I:\user\03270815-am.wpd